

### **DETAILED ACTION**

Claims 51 and 52 are currently pending and are rejected.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 26 May 2009 and 27 April 2009 have been entered.

#### ***Response to Amendment and Arguments***

Applicants' amendment and arguments filed 27 April 2009 have been considered and entered into the instant application. The amendment has introduced new matter into the application, see the 35 USC 112 1<sup>st</sup> paragraph rejection below. The amendment and arguments filed 27 April 2009 have overcome the objection to claim 51 for the typographical error and have overcome the 35 USC 103(a) rejection as the instant claims are for the multi-step batch preparation of a compound II. The prior art references isolate the intermediate compounds used in the preparation of the formula II compound whereas the instant claims do not isolate the intermediates but continue onto the next step. For example, wherein the instant formula IV is extracted as an organic phase and added to the polar solvent, the prior art isolates the formula IV. According to *In re Freed*, 415 F.2d 785, 165 USPQ 519 (CCPA 1970) wherein the performance of a prior art "two-pot" process as a "one-pot" process may be evidence of nonobviousness

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because it can be logically assumed that the prior art set forth the least number of steps thought necessary. There are two instances wherein the prior art references isolate compounds, compound IV and V. The instantly claimed process neither isolates compound IV or V. The 35 USC 103(a) rejection is therefor withdrawn.

### ***Specification***

The disclosure is objected to because of the following informalities: Specifically, the disclosure should have a section entitled --CROSS-REFERENCE TO RELATED APPLICATIONS--after the title of the invention which contains the continuing data for the instant application.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51 and 52 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims contain the phrase "multi-step batch" which is considered new matter as this phrase is found nowhere in applicants' originally filed disclosure or claims. Applicant's have not provided where the phrase "multi-step batch" appears in the specification by page number and line number

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but has only provided the statement that the clarification is found, inter alia, in Example

1. However, it is noted that Example I is a “species” of the claimed invention and that example I also does not have the phrase “multi-step batch”. A species does not support the limitation of a genus to a new sub-genus. Additionally, it is noted that example I has isolation steps on lines 18 and 33 of page 10. Claims which change the scope relative to the originally filed claims may lack written description, see *In re Ruschig*, 371 F.2d 990, 154 USPQ 118 (CCPA) 1967) which supports that the original disclosure of a large genus did not support a later filed claim to a previously unnamed single species.

Furthermore, Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir.2000) notes that with respect to In re Ruschig, that “Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say “here is my invention”. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.” It is suggested that applicant delete the phrase “multi-step batch” from the claims 51 and 52 and insert in its place the phrase “one-pot” which is supported in the instant specification, for example, at least on page 4.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/  
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3 August 2009

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